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### REMARKS

Reconsideration and the timely allowance of the pending claims, in view of the following remarks, are respectfully requested.

In the Final Office Action dated March 9, 2006, the Examiner rejected claims 13-18, 63-65, 67-78, 80-88, and 90-91, under 35 U.S.C. §103(a), as allegedly being unpatentable over Thompson '166 (U.S. Patent No. 4,710,166) in view of Wortrich '643 (U.S. Patent No. 4,750,643) and Kampfe '847 (U.S. Patent No. 5,450,847); rejected claims 13-18, 63-65, 67-78, 80-88, and 90-91, under 35 U.S.C. §103(a), as allegedly being unpatentable over Orkin '444 (U.S. Patent No. 4,925,444) in view of Wortrich '643 and Kampfe '847; and rejected claims 13-18, 63-65, 67-78, 80-88, and 90-91, under 35 U.S.C. §103(a), as allegedly being unpatentable over Kerns '706 (U.S. Patent No. 4,756,706) in view of Kampfe '847 and Wortrich '643.

By this Amendment, Applicant has amended claims 13, 67, 72, and 82 to provide a clearer presentation of the claimed invention. Applicant submits that no new matter has been introduced.

In addition, Applicant still requests the return of a copy of the initialed PTO-1449 forms in connection with the IDS filed on November 10, 2004.

Applicant respectfully traverses the prior art rejections, under 35 U.S.C. §103(a), for the following reasons:

I. Prior Art Rejections Under §103(a).

As a preliminary matter, Applicant respectfully notes that while “every point in the prior action of an Examiner which is still applicable must be repeated or referred to”, the PTO Guidelines mandate that “where the applicant traverses any rejection, *the examiner should, if he or she repeats the rejection, take note of the applicant’s argument and answer the substance of it.*” (See MPEP 707.07(e)-(f)) (*emphasis added*).

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With this said, Applicant respectfully submits that the pending Final Office Action is *not complete* as to all matters, because the Examiner has not provided reasons/explanations as to why all of the limitations of the amended set of claims filed with the PTO in the previous Amendment of August 15, 2005 are rendered obvious in view of the art of record. That is, despite the fact that the previous Amendment contains significant changes to the claim language including new claim limitations, the pending Final Office Action appears to be a cut-and-paste regurgitation of the previous Office Action dated May 4, 2005, without any regard to, or discussion of, the new claim language and limitations set forth in the amended set of claims of August 15, 2005.

Applicant further points out that sustaining the finality of the pending Final Office Action, without giving an adequate basis for rejecting the claims as they currently stand, places an undue burden on the Applicant to guess what the Examiner is trying to assert and is, thus, manifestly unfair. Unless the Examiner issues a notice immediately allowing all pending claims, Applicants respectfully and strongly request the withdrawal of the finality of the pending Final Office Action and that a supplemental Office Action be issued that completely and fairly addresses each of the claim limitations as they stand relative to this Amendment.

With respect to the “substantive” prior art rejections, the Examiner asserted that claims 13-18, 63-65, 67-78, 80-88, and 90-91 are rendered obvious by the combination of Thompson ‘166, Worrich ‘643, and Kampfe ‘847. Applicant strongly disagrees.

At the outset, Applicant first reminds the Examiner that, in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. As a corollary to this requirement, the Federal Circuit has specifically held that the mere fact that *the prior art could be modified* as proposed by the Examiner *is not sufficient* to establish a *prima facie* case of obviousness. (See, *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (*emphasis added*). Rather, the Examiner *must explain why the prior art would have suggested* to

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one of ordinary skill in the art *the desirability of the modification*. (See *Fritch*, 972 F.2d at 1266, 23 USPQ2d at 1783-84)(*emphasis added*).

Second, there must be a reasonable expectation of success. And third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (See, MPEP 2142).

Applicant respectfully submits that none of these criteria has been met. Therefore, it is respectfully submitted that the Office Action has failed to establish a *prima facie* case that would render claims 13-18, 63-65, 67-78, 80-88, and 90-91 obvious.

In particular, as identified above in the claims list section, independent claim 13, sets forth a *method of delivering fluid to multiple patients*. In so doing, claim 13 positively recites providing a fluid delivery system comprising a reusable portion and a plurality of per-patient disposable portions, and connecting the second end of a first per-patient disposable portion of the per-patient disposable portions to the reusable portion and the first end of the first per-patient disposable portion to a first patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient. Claim 13 also positively recites selectively delivering fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, disconnecting the first per-patient disposable portion from the reusable portion and the first patient, connecting a second per-patient disposable portion to the reusable portion to a second patient of the multiple patients, and selectively delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion.

In dramatic contrast, Applicant notes that the Thompson '166 reference teaches a *system* for the sequential delivery of two fluids to *a single patient*. (See Thompson '166: col. 3, lines 51 – 52). In fact, Thompson '166 provides a comprehensive explanation of the importance of reducing entry trauma to *a single patient* when sequentially administering medicaments. (See Thompson '166: col. 1, lines 9-25). In so doing, there is not even a remote suggestion or inference that the Thompson '166

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system is capable of providing a *method of delivering fluid to multiple patients*, as required by claim 13. Nor is there anything in Thompson '166 that teaches or suggests connecting the second end of a first per-patient disposable portion of the plurality of per-patient disposable portions to the reusable portion and the first end of the first per-patient disposable portion to a first patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient and to selectively deliver fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, as also required by claim 13. In addition, there is nothing in Thompson '166 that teaches or suggests connecting a second per-patient disposable portion to the reusable portion and a second patient of the multiple patients and selectively delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion, as also required by claim 13.

Despite the Examiner's contentions, none of the remaining references cure the deficiencies of Thompson '166 noted above. For example, the Kampfe '847 reference is directed to a system and method of preparing and mixing suitable dosage forms of fluid contrast medium for individual examination. (See Kampfe '847: col. 3, lines 10-20). There is nothing in Kampfe '847, however, that remotely suggests *the direct dispensation of fluids to a patient* - much less provide a *method of delivering fluid to multiple patients*, as required by claim 13. Moreover, Kampfe '847, clearly fails to teach or suggest connecting the second end of a first per-patient disposable portion of the plurality of per-patient disposable portions to the reusable portion and the first end of the first per-patient disposable portion to a first patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient and selectively delivering fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, as also required by claim 13. In addition, there is nothing in Kampfe '847 that teaches or suggests connecting a second per-patient disposable portion to the reusable portion and a second patient of the multiple patients and selectively delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion, as also required by claim 13..

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Regarding the last reference, Wortrich '643 is directed to a system and method for dispensing fluid 12 from a *single container* 10 to a succession of multiple patients. (See Wortrich '643: col. 3, line 14 – col. 4, line 39; *see also* Abstract; FIG. 1). As such, Wortrich '643 is incapable of teaching a method of delivering two fluids to multiple patients. There is also nothing in Wortrich '643 that teaches the use of a second fluid source and a device adapted to mix fluids from the first and second fluid sources.

In addition to the lack of claim elements taught by the asserted references, Applicants submit the establishment of a *prima facie* case of obviousness requires that there must at least be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. And, as noted above, the issue is not whether *the prior art could be modified* – rather, the issue is that the Examiner *must explain why the prior art would have suggested* to one of ordinary skill in the art *the desirability of the modification*. In this case, the Examiner has neither identified where the suggestion or motivation lies to combine the teachings of the prior art nor has he explained why the prior art suggests the desirability of such a modification. Merely stating that there may be some economic benefit is clearly insufficient to establish a *prima facie* case of obviousness.

Applicant and Representatives are, therefore, at a loss as to how the Thompson '166, Wortrich '643, and Kampfe '847 references could possibly be combined, as there is absolutely no suggestion in any of the references to combine and/or modify the features to render a method of delivering fluids to multiple patients, as set forth in claim 13. As noted above, each of the references have disparate objectives resulting in incompatible configurations. So to say that it would be obvious to combine the teachings of these references is either based on an unreasonable leap of faith, a lack of ordinary skill in the art, or impermissible hindsight.

Finally, with respect to this set of rejections, the Examiner maintains that the use of multiple infusion lines is a mere duplication of parts that has been found by the courts as only taking routine skill in the art. Applicant assumes that the Examiner relied on the old, *per se* rule of *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA

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1960), which has been distinguished on many grounds. Indeed, in *Ex parte Granneman*, 68 USPQ2d 1219 (Bd. Pat. App. & Int. 2003), the Board of Patent Appeals and Interferences rebuked the use of the *per se Harza* rule by stating that “reliance on *per se* rules of obviousness is legally incorrect and must cease.” (*Granneman*, 68 USPQ2d at 1221)(quoting, *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995)).

Like the *Granneman* case, the Examiner does not explain why, based on the comparison between the facts of *Harza* and the claimed invention, the legal conclusion should be the same as that of *Harza*. Applicant points out that the *per se Harza* rule has no application or bearing in situations where the prior art teaching is directed to accomplishing a function for a single user, such as delivering fluids to a single patient, while the claimed invention is directed to accomplishing a function for multiple users, such as delivering fluids to multiple patients. By its very nature, the latter function may require multiple parts in order to operate for its intended purpose and such multiple parts must be given patentable weight consistent with basic claim construction and obviousness analysis principles. The use of multiple parts cannot be summarily vitiated without being given its due consideration.

The Examiner also asserted that claims 13-18, 63-65, 67-78, 80-88, and 90-91 are rendered obvious by the combination of Orkin '444, Wortrich '643, and Kampfe '847. Applicants respectfully disagree.

The Orkin '444 reference is directed to a closed, multiple-fluid delivery system that can deliver a plurality of preselected fluids in a preselected sequence via a closed fluid-flow delivery system to an output port *for a single patient*. (See Orkin '444: col. 3, lines 34-38; see also Abstract). In fact, much like the Thompson '166 reference, Orkin '444 provides the importance of reducing the potential entrance of infections to a *single patient* when sequentially administering medicaments. (See Orkin '444: col. 1, lines 28-36). As such, there is nothing in Orkin '444 that is remotely capable of providing a *method of delivering fluid to multiple patients*, as required by claim 13. Nor is there anything in Orkin '444 that teaches or suggests connecting the second end of a first per-patient disposable portion of the plurality of per-patient disposable

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portions to the reusable portion and the first end of the first per-patient disposable portion to a first patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient and to selectively deliver fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, as also required by claim 13. In addition, there is nothing in Orkin '444 that teaches or suggests connecting a second per-patient disposable portion to the reusable portion and a second patient of the multiple patients and selectively delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion, as also required by claim 13.

For reasons already discussed above, the remaining references, Worrich '643, and Kampfe '847, are incapable of curing the deficiencies of Orkin '444 noted above. Moreover, as also discussed at length above, by virtue of their objectives and disclosures, there is no reason for combining the Orkin '444, Worrich '643, and Kampfe '847 references, as there is absolutely no suggestion in any of the references to combine and/or modify the features to render a method of delivering fluids to multiple patients, as set forth in claim 13.

Finally, the Examiner asserted that claims 13-18, 63-65, 67-78, 80-88, and 90-91 are rendered obvious by the combination of Kerns '706, Worrich '643, and Kampfe '847. Applicants respectfully disagree.

The Kerns '706 reference solely directed to a system that employs a plurality of infusion pump modules that are detachably connected to a portable central management unit that programs the modules. (See Kerns '706: col. 1, lines 9-12, lines 41-53). Kerns '706 discloses the use of a central management unit 14 which is permanently attached to an infusion pump unit 16, three removable modules, such as, blood pressure monitor 18, an oxymeter 20, and a second infusion pump module 22, IV bottles 28, 30, and piggyback bottle 36. The output of pump modules 16 and 22 consists of cannulae 54, 56, respectively, which are to be inserted to a patient. (See Kerns '706: col. 2, lines 49-62; col. 3, lines 15-18).

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However, like the Thompson '166 and Orkin '444 primary references, Kerns '706 is directed to delivering a plurality of fluids to *a single patient*. As such, there is nothing in Kerns '706 that is remotely capable of providing a *method of delivering fluid to multiple patients*, as required by claim 13. Nor is there anything in Kerns '706 that teaches or suggests connecting the second end of a first per-patient disposable portion of the plurality of per-patient disposable portions to the reusable portion and the first end of the first per-patient disposable portion to a first patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient and to selectively deliver fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, as also required by claim 13. In addition, there is nothing in Kerns '706 that teaches or suggests connecting a second per-patient disposable portion to the reusable portion and a second patient of the multiple patients and selectively delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion, as also required by claim 13.

For reasons already discussed above, the remaining references, Wortrich '643, and Kampfe '847, are incapable of curing the deficiencies of Kerns '706 noted above. Moreover, as also discussed at length above, by virtue of their objectives and disclosures, there is no reason for combining the Kerns '706, Wortrich '643, and Kampfe '847 references, as there is absolutely no suggestion in any of the references to combine and/or modify the features to render a method of delivering fluids to multiple patients, as set forth in claim 13.

For at least these reasons, Applicant submits that none of the applied references, can be reasonably combined to teach the claimed combination of elements recited by amended claim 13. As such, claim 13 is clearly patentable over these references. Applicant, therefore, respectfully requests the withdrawal of the rejection of claim 13, under §103(a).



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Moreover, because claims 14-16, 64-65, 69, 72-75, and 78 depend, either directly or indirectly from claim 13, these claims are patentable at least by virtue of dependency as well as for their additional recitations.

In addition, independent claims 72 and 82 recite similar features to claim 13 that have been proven to be patentable over the applied references, so that claims 72 and 82 are patentable for at least the reasons given with respect to claim 13. Further, because claims 73-78 and 80-81 depend from claim 72 and claims 83-88 and 90-91 depend from claim 82, claims 73-78 and 80-81 and claims 83-88 and 90-91 are patentable at least by virtue of dependency as well as for their additional recitations.

**II. Conclusion.**

All matters having been addressed and in view of the foregoing, Applicant respectfully requests the entry of this Amendment, the Examiner's reconsideration of this application, and the immediate allowance of all pending claims. In the alternative, Applicants respectfully and strongly request the withdrawal of the finality of the pending Final Office Action and that a supplemental Office Action be issued that completely and fairly addresses each of the claim limitations as they stand relative to the present Amendment.

Applicant submits that the entry of this Amendment is proper under 37 C.F.R. §1.116 as the claim changes: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not require any further consideration as the claim features should have already been searched; and (c) places the application in better form for an Appeal, should an Appeal be necessary.

Applicant's Counsel remains ready to assist the Examiner in any way to facilitate and expedite the prosecution of this matter. If any point remains in issue in which the Examiner feels may be best resolved through a personal or telephone interview, please contact the Undersigned at the telephone number listed below.

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Please charge any fees associated with the submission of this paper to Deposit Account Number 13-2530. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,



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